

**IN RE: AVANDIA MARKETING, SALES  
PRACTICES AND PRODUCTS LIABILITY  
LITIGATION**

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**THIS DOCUMENT APPLIES TO:**  
*Siddoway v. GSK*

**09-5599**

Plaintiffs subsequently sued GSK, raising nine claims against the drug manufacturer: (1) negligence, (2) strict liability, (3) failure to warn, (4) breach of express warranty, (5) breach of implied warranty, (6) breach of implied warranty of merchantability, (7) negligent misrepresentation, (8) violation of Utah's Consumer Protection Sales Act, and (9) loss of consortium. GSK now moves for summary judgment, arguing that all of Plaintiffs' claims are premised on GSK's alleged failure to adequately warn of an increased risk of heart attack associated with Avandia use, and Plaintiffs are unable offer evidence showing that GSK's failure

to warn of this association was the proximate cause of Mr. Siddoway's injuries. For reasons that follow, the Court will grant the motion.

## **I. FACTUAL AND PROCEDURAL BACKGROUND**

### **A. MR. SIDDOWAY'S HEALTH HISTORY**

Mr. Siddoway was diagnosed with Type II diabetes by his primary care physician, Dr. Peterson. Dr. Peterson initially prescribed Metformin and Amaryl (a sulfonylurea), two common diabetes medications, to treat Mr. Siddoway. On July 6, 2001, however, Dr. Peterson replaced the Amaryl prescription with Avandia. Dr. Peterson prescribed Avandia to Mr. Siddoway until May 22, 2002. His last office visit with Mr. Siddoway was in October 2002.

In July 2003, Mr. Siddoway suffered a heart attack and underwent stent replacement surgery. In October 2003, he suffered another heart attack and needed a heart transplant, which he received in December 2003. Following the heart transplant, a different doctor—Dr. Edward Gilbert—prescribed Avandia to Mr. Siddoway. Mr. Siddoway continued to take Avandia from December 2003 through June 2007, and did not experience any other adverse cardiovascular condition or event. Mr. Siddoway does not smoke or drink alcohol and is not obese.<sup>1</sup>

### **B. THE AVAILABILITY OF INFORMATION ABOUT AVANDIA AND AN INCREASED RISK OF HEART ATTACK**

When Avandia was initially approved by the FDA in 1999 to treat Type II diabetes, the drug's package insert ("label") contained no warning of an increased risk of heart attack. On May 21, 2007, however, the FDA issued a safety alert for Avandia, notifying consumers that "data from controlled clinical trials have shown that there is a potentially significant increase in the risk of heart attack and heart-related deaths in patients taking Avandia."<sup>2</sup> Although this

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<sup>1</sup> Pls.' Resp. to Mot. for Summ. J. at 2.

<sup>2</sup> *Id.*, Ex. 2 at 1.

safety alert acknowledged that the data from clinical trials “provide[d] contradictory evidence about the risks in patients treated with Avandia,” it nonetheless sought to warn consumers of a potential risk of heart attack and encouraged patients taking Avandia to discuss treatment options with their physicians.<sup>3</sup> At this time, the FDA directed GSK to add this information in a boxed warning on the Avandia label.

After this change to the label and after Plaintiffs filed this lawsuit, GSK and the FDA conducted extensive research on Avandia’s safety. In 2013, the FDA ultimately concluded that there was no increased risk of heart attack associated with Avandia use compared to alternative diabetes medications. In a decisional memorandum dated November 19, 2013, the FDA wrote that the data “support no statistically significant difference between rosiglitazone [Avandia] and metformin/sulfonylurea for the risk of death or major adverse cardiovascular outcomes, other than the known class effect of heart failure.”<sup>4</sup> Rather, re-adjudication of long-term trials of Avandia “provide[d] considerable reassurance regarding the cardiovascular safety of rosiglitazone.”<sup>5</sup> Therefore, in 2014, the FDA approved an updated Avandia label that removed the boxed warning for a potential increased risk of heart attack.

## **II. STANDARD OF REVIEW**

Upon motion of a party, summary judgment is appropriate if “the materials in the record” show “that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”<sup>6</sup> Summary judgment may be granted only if the moving party persuades the district court that “there exists no genuine issue of material fact that would permit

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<sup>3</sup> *Id.*

<sup>4</sup> Def.’s Reply, Ex. A at 20.

<sup>5</sup> *Id.*, Ex. A at 21.

<sup>6</sup> Fed. R. Civ. P. 56(a), (c)(1)(A).

a reasonable jury to find for the nonmoving party.”<sup>7</sup> A fact is “material” if it could affect the outcome of the suit, given the applicable substantive law.<sup>8</sup> A dispute about a material fact is “genuine” if the evidence presented “is such that a reasonable jury could return a verdict for the nonmoving party.”<sup>9</sup>

In evaluating a summary judgment motion, a court “must view the facts in the light most favorable to the non-moving party,” and make every reasonable inference in that party’s favor.<sup>10</sup> Further, a court may not weigh the evidence or make credibility determinations.<sup>11</sup> Nevertheless, the party opposing summary judgment must support each essential element of the opposition with concrete evidence in the record.<sup>12</sup> “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.”<sup>13</sup> This requirement upholds the “underlying purpose of summary judgment [which] is to avoid a pointless trial in cases where it is unnecessary and would only cause delay and expense.”<sup>14</sup> Therefore, if, after making all reasonable inferences in favor of the non-moving party, the court determines that there is no genuine dispute as to any material fact, summary judgment is appropriate.<sup>15</sup>

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<sup>7</sup> *Miller v. Ind. Hosp.*, 843 F.2d 139, 143 (3d Cir. 1988).

<sup>8</sup> *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

<sup>9</sup> *Id.*

<sup>10</sup> *Hugh v. Butler Cnty. Family YMCA*, 418 F.3d 265, 267 (3d Cir. 2005).

<sup>11</sup> *Boyle v. Cnty. of Allegheny*, 139 F.3d 386, 393 (3d Cir. 1998).

<sup>12</sup> *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).

<sup>13</sup> *Anderson*, 477 U.S. at 249-50 (citations omitted).

<sup>14</sup> *Walden v. Saint Gobain Corp.*, 323 F. Supp. 2d 637, 641 (E.D. Pa. 2004) (citing *Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir. 1976)).

<sup>15</sup> *Celotex*, 477 U.S. at 322; *Wisniewski v. Johns-Manville Corp.*, 812 F.2d 81, 83 (3d Cir. 1987).

### III. DISCUSSION

The parties agree that Utah law governs this case.<sup>16</sup> The Court will begin by examining Plaintiffs' negligence and failure to warn claims. Then, the Court will address Plaintiff's remaining claims.

#### A. PLAINTIFFS' NEGLIGENCE & FAILURE TO WARN CLAIMS

Plaintiffs raise negligence and failure to warn claims against GSK. Both causes of action essentially allege that GSK negligently failed to warn Plaintiffs of the increased risk of heart attack purportedly associated with Avandia use.<sup>17</sup>

GSK acknowledges that it had a duty to warn of risks associated with Avandia; however, it argues that any breach of this duty to warn was not the proximate cause of Mr. Siddoway's injuries and thus, the negligence and failure to warn claims must fail under the learned intermediary doctrine.<sup>18</sup>

Under Utah's learned intermediary doctrine, "manufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, not the end user or patient."<sup>19</sup> "The contours of this duty include making 'timely and adequate warnings to the medical profession of

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<sup>16</sup> The Siddoways were residents of Utah at all relevant times, and the lawsuit was originally filed in Utah. GSK is a Delaware corporation with its principal place of business in Pennsylvania. Mr. Siddoway was prescribed Avandia by a doctor in Utah; he received treatment and was provided warnings about the risks of Avandia in Utah. He suffered the heart attacks in Utah. Accordingly, the Court will apply the substantive law of Utah.

<sup>17</sup> See Compl. at ¶ 26 (In the first cause of action for negligence, Plaintiffs allege that GSK "negligently failed to issue warnings, recall Avandia, . . . or otherwise act properly and timely to alert the public of the damages inherent in Avandia" to prevent Mr. Siddoway's injuries); see also *id.* at ¶ 37 (In the third cause of action for failure to warn, Plaintiffs allege that GSK "failed to provide adequate warnings to users or consumers of the product and continued to aggressively promote Avandia").

<sup>18</sup> To establish a negligence claim under Utah law, a "plaintiff must show: (1) that the defendant owed the plaintiff a duty, (2) that the defendant breached that duty, (3) that the breach of duty was the proximate cause of the plaintiff's injury, and (4) that the plaintiff in fact suffered injuries or damages." *Tingley v. Radionics*, 193 F. App'x 747, 759-60 (10th Cir. 2006) (internal quotation marks and citation omitted); *Cope v. Utah Valley State Coll.*, 342 P.3d 243, 248 (Utah 2014).

<sup>19</sup> *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928 (Utah 2003) (citation omitted).

any dangerous side effects produced by its drug of which it knows or has reason to know.’”<sup>20</sup>

After receiving warnings from the drug manufacturer, the physician acts as a learned intermediary between manufacturer and patient.<sup>21</sup> In this way, the physician is “best situated to weigh the risks and benefits” associated with a drug in relation to the needs of the patient.<sup>22</sup>

“In any failure to warn claim, a plaintiff must show that the failure to give an adequate warning in fact caused the injury; i.e., that had warnings been provided, the injured party would have altered his use of the product or taken added precautions to avoid the injury.”<sup>23</sup> If the event that produced the plaintiff’s injury would have occurred regardless of the defendant’s conduct, then the failure to warn is not the proximate cause of the harm and the plaintiff’s claim fails.<sup>24</sup> Thus, under the learned intermediary doctrine, to establish that the defendant’s failure to warn is a proximate cause of the plaintiff’s injury, the prescribing physician must testify that a different warning would have caused the doctor to alter his or her prescribing program for the plaintiff patient.

Mr. Siddoway’s prescribing physician, Dr. Peterson, testified about his opinion on Avandia’s association with an increased risk of heart attack. His testimony is crucial to the disposition of this motion. During his deposition in 2015, Dr. Peterson was asked whether his prescribing choices would have changed if he had all the current and historical information on Avandia’s association with heart attacks, and he responded that his choices would have remained the same:

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<sup>20</sup> *Christison v. Biogen Idec, Inc.*, 199 F. Supp. 3d 1315, 1319 (D. Utah 2016) (quoting *Schaerrer*, 79 P.3d at 928-29).

<sup>21</sup> *Id.*

<sup>22</sup> *Fisher v. Professional Compounding Centers of America, Inc.*, 311 F. Supp. 2d 1008, 1020 (D. Nev. 2004) (citing *Schaerrer*, 79 P.3d at 928-29).

<sup>23</sup> *House v. Armour of America, Inc.*, 929 P.2d 340, 346 (Utah 1996).

<sup>24</sup> *Id.*

Q: The FDA said, first, in that paragraph [of the November 2013 FDA Decisional Memo] I was reading to you before, “The RECORD trial establishes that long-term rosiglitazone use is not associated with an unacceptably increased CV risk that would outweigh rosiglitazone’s benefit and warrant removal from the market when rosiglitazone is compared to standard-of-care comparators.” My question for you is, is that consistent with your view of the data, as you sit here today, in terms of the cloud being removed from Avandia based upon the RECORD re-adjudication?

A: Yes.

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Q: What does this mean to you as of May of 2014 relative to Avandia and whether it has been demonstrated to have a meaningful cardiovascular risk in comparison to other antidiabetic agents?

A: It’s consistent with my general impression that cardiovascular risk was not a true component of Avandia’s effect on patients.

Q: And was that the understanding that you had when you first prescribed Avandia to Mr. Siddoway?

A: It’s the same.

Q: It’s the same.

A: Yeah. It’s more informed now.

Q: It’s more informed now. But in terms of what would be Avandia’s cardiovascular risk profile, if you will, is the same now as your understanding of it was when you prescribed it to Mr. Siddoway in 2001; is that correct?

A: Yes.

Q: And if this label that’s there today were the label for Avandia in effect at the time Mr. Siddoway was in your office and you were considering using Avandia in 2001, would you have prescribed Avandia just the same way you did then under a different label?

A: Yes.<sup>25</sup>

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<sup>25</sup> Dr. Peterson Tr. at 110:13-113:3 (objections omitted).

From this testimony, it is clear that Dr. Peterson’s understanding of Avandia’s risk profile today is the same as it was when he prescribed Avandia to Mr. Siddoway—that Avandia is not associated with an increased cardiovascular risk compared to other diabetes drugs.<sup>26</sup> He also testified that, if the current package insert were in place when he was prescribing Avandia to Mr. Siddoway, he still would have prescribed it.

In light of Dr. Peterson’s testimony that he would have made the same prescribing decision for Mr. Siddoway with the information available today, it falls to Plaintiffs to point to some evidence suggesting that Dr. Peterson equivocated on his position, creating a genuine issue of material fact. Plaintiffs, however, are unable to do so.

Although Plaintiffs point to Dr. Peterson’s testimony that Avandia “faded from [his] use” in 2007 shortly after the Nissen analysis was released,<sup>27</sup> which suggested a potential increased risk of heart attack, he also testified that the concerns of the Nissen analysis have been shown not to be true.<sup>28</sup> Plaintiffs also identify Dr. Peterson’s testimony that he “quit using” Avandia for patients after 2007.<sup>29</sup> However, Dr. Peterson’s undisputed testimony is that, even when the 2007 data on which Plaintiffs base their claims is considered along with the other Avandia risk data available today, he would still prescribe Avandia to Mr. Siddoway, just as he had in 2001 and 2002, when there was no heart attack risk warning in the Avandia label. Thus, the testimony Plaintiffs identify is not sufficient to establish a genuine issue of material fact as to whether such

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<sup>26</sup> *Id.* at 111:25-112:19; 186:15-24.

<sup>27</sup> *Id.* at 28:17-29:6.

<sup>28</sup> *Id.* at 16:22-17:6.

<sup>29</sup> *Id.* at 29:20-23.



a warning would have deterred him from prescribing Avandia to Mr. Siddoway *before* he suffered the 2003 heart attacks.<sup>30</sup>

When all risk information is considered by Dr. Peterson, he testified that he would still prescribe Avandia for Mr. Siddoway, as he had done. Plaintiffs have failed to establish a genuine issue of material fact as to whether Dr. Peterson would have prescribed a different medication for Mr. Siddoway, rather than Avandia, prior to his injuries in 2003, if GSK had provided a warning regarding a risk of heart attacks.<sup>31</sup> Because Plaintiffs have failed to establish an issue for trial with regard to whether GSK's conduct was a proximate cause of Mr. Siddoway's injuries, Plaintiffs' negligence and failure to warn claims must be dismissed.

#### **B. PLAINTIFF'S REMAINING CLAIMS**

Next, the Court must determine whether any of Plaintiffs' remaining claims may proceed. In addition to the negligence and failure to warn claims, Plaintiffs raised claims of strict liability, breach of express warranty, breach of implied warranty, breach of implied warranty of merchantability, negligent misrepresentation, violation of Utah's Consumer Protection Sales Act, and loss of consortium, which rely in this case on GSK's failure to include proper warnings.

Under Utah law, proximate causation is an element of Plaintiffs' remaining strict liability,<sup>32</sup> breach of express warranty,<sup>33</sup> breach of implied warranty,<sup>34</sup> breach of implied

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<sup>30</sup> Plaintiffs also take issue with the fact that Dr. Peterson initially thought that he would be asked about Avandia's possible link to bladder cancer, from which Mr. Siddoway also suffered, rather than a potential increased risk of heart attack. However, Dr. Peterson's preparation has no bearing on the actual testimony provided during the deposition, and the Complaint plainly relates to the heart attacks Mr. Siddoway suffered. Thus, any confusion about bladder cancer at the outset of the deposition does not affect this case, and does not establish a genuine issue of material fact to survive summary judgment.

<sup>31</sup> See *Coburn v. SmithKline Beecham Corp.*, 174 F. Supp. 2d 1235, 1239 (D. Utah 2001) (stating that the duty to warn arises based on what the manufacturer knows or should know about a risk associated with its product and framing that duty to warn issue as whether the manufacturer was aware of the alleged risks at the time the plaintiff took the prescription medication, not based on what was learned at a later time) (citations omitted).

<sup>32</sup> See *Wankier v. Crown Equip. Corp.*, 353 F.3d 862, 866-67 (10th Cir. 2003) ("To plead a case of strict products liability against a manufacturer, a plaintiff must allege . . . that the defective condition was a cause of the plaintiff's injuries.") (citations omitted).

warranty of merchantability,<sup>35</sup> and negligent misrepresentation claims.<sup>36</sup> In addition, the Utah Consumer Sales Practice Act (“UCSPA”) requires that a consumer asserting a claim for violation of the UCSPA show that the loss was suffered “as a result of a violation.”<sup>37</sup> Thus, Plaintiffs have the burden of establishing proximate causation to sustain these claims. However, like the negligence and failure to warn claims, Plaintiffs cannot meet this burden because Dr. Peterson testified that even if he were in possession of all the information that is contained in the Avandia label today when he originally prescribed Avandia to Mr. Siddoway, he still would have made the same prescribing decision. Therefore, these claims fail.

Last, under Utah law, either spouse may bring a claim against a third party for loss of consortium, so long as the injured spouse has suffered “a significant permanent injury . . . that substantially changes that person’s lifestyle.”<sup>38</sup> A loss of consortium claim, however, is derivative of the injured spouse’s underlying personal injury claims.<sup>39</sup> Where, as here, the

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<sup>33</sup> See *SME Indus., Inc. v. Thompson, Ventulett, Stainback & Assocs., Inc.*, 28 P.3d 669, 677 (Utah 2001) (“As an initial matter, in order to recover under a theory of breach of express warranty, plaintiff must prove, in addition to the existence of the warranty, that breach of the warranty is the ‘direct and proximate cause of the damage.’”) (citations omitted).

<sup>34</sup> See, e.g., *Fitz v. Synthes USA*, 990 P.2d 391, 393 (Utah 1999) (identifying proximate cause as an element to a claim of breach of implied warranty in a suit involving allegedly defective bone screws).

<sup>35</sup> See *Kirkbide v. Terex USA, LLC*, 798 F.3d 1343, 1354 (10th Cir. 2015) (“We note that for purposes of a tort claim for breach of the implied warranty of merchantability, Utah law provides that the warranty is breached only if the plaintiff establishes the elements of a strict-products-liability claim for defective manufacture, defective design, or failure to warn.”) (citation omitted).

<sup>36</sup> See *Lundgren v. Matrixx Initiatives, Inc.*, No. 10-128, 2013 WL 3087726, at \*1 (D. Utah June 18, 2013) (noting that a plaintiff must demonstrate a causal link between the plaintiff’s injury and the defendant’s conduct to establish a misrepresentation claim).

<sup>37</sup> See Utah Code Ann. § 13-11-19(2) (“A consumer who suffers a loss as a result of a violation of this chapter may recover, but not in a class action, actual damages or \$2,000, whichever is greater, plus court costs.”); see also *Andreason v. Felsted*, 137 P.3d 1, 3 (Utah Ct. App. 2006) (“[U]nder section 13-11-19, a consumer can bring a private action when the UCSPA has been violated and when the consumer can show he suffered a ‘loss’ that is causally connected to the violation.”).

<sup>38</sup> See Utah Code Ann. § 30-2-11(1)-(2); see also *Alusa v. Salt Lake Cnty.*, No. 11-184, 2013 WL 3946574, at \*13 (D. Utah Aug. 1, 2013).

<sup>39</sup> See Utah Code Ann. § 30-2-11(5) (“The spouse’s action for loss of consortium: (a) shall be derivative of the cause of action existing on behalf of the injured person; and (b) may not exist in cases where the injured person would not have a cause of action.”).

underlying personal injury claims fail, the loss of consortium claim will also fail. Thus, Mrs. Siddoway's derivative claim of loss of consortium must also be dismissed.

#### **IV. CONCLUSION**

For the foregoing reasons, GSK's motion for summary judgment will be granted and the claims will be dismissed with prejudice. An appropriate order follows.